

TUBULAR STRUCTURE/STENT/STENT SECUREMENT MEMBER**FIELD OF THE INVENTION**

[0001] The present invention relates to an implantable endoluminal prosthesis. More particularly, the present invention relates to a stent-graft endoluminal prosthesis offering increased flexibility and compliance.

BACKGROUND OF THE INVENTION

[0002] An endoluminal prosthesis is a medical device commonly known to be used in the treatment of diseased blood vessels. An endoluminal prosthesis is typically used to repair, replace, or otherwise correct a damaged blood vessel. An artery or vein may be diseased in a variety of ways. An endoluminal prosthesis is therefore designed to be used to prevent or treat a wide variety of defects such as stenosis of the vessel, thrombosis, occlusion, or an aneurysm.

[0003] One type of endoluminal prosthesis used in the repair of diseases in various body vessels is a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract and bile duct, as well as in a variety of other applications in the body. Endovascular stents have become widely used for the treatment of stenosis, strictures, and aneurysms in various blood vessels. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the vessel.

[0004] Stents are generally open ended and are radially expandable between a generally unexpanded insertion diameter and an expanded implantation diameter which is greater than the unexpanded insertion diameter. Stents are often flexible in configuration, which allows them to be inserted through and conform to tortuous pathways in the blood vessel. The stent is generally inserted in a radially compressed state and expanded either through a self-expanding mechanism,

or through the use of balloon catheters.

[0005] A graft is another type of endoluminal prosthesis which is used to repair and replace body vessels. Whereas a stent provides structural support to hold a damaged vessel open, a graft provides an artificial lumen through which blood may flow. Grafts are tubular devices which may be formed of a variety of materials, including textile and non-textile materials. One type of non-textile material particularly suitable for use as an implantable prosthesis is polytetrafluoroethylene (PTFE). PTFE exhibits superior biocompatibility and low thrombogenicity, which makes it particularly useful as vascular graft material in the repair or replacement of blood vessels. In vascular applications, the grafts are manufactured from expanded PTFE (ePTFE) tubes. These tubes have a microporous structure which allows natural tissue ingrowth and cell endothelialization once implanted in the vascular system. This contributes to long term healing and patency of the graft.

[0006] It is also known to combine a stent and a graft to form a composite medical device. Such a composite medical device provides additional support for blood flow through weakened sections of a blood vessel. In endovascular applications the use of a stent/graft combination is becoming increasingly important because the combination not only effectively allows the passage of blood therethrough, but also ensures the implant will remain open.

[0007] Several types of stent/graft inventions are known in the art. U.S. Patent No. 5,151,105 issued to Kwan-Gett discloses a collapsible textile vessel sleeve with stent members positioned at opposite ends of the sleeve. The device is specifically designed to provide a vessel sleeve that is collapsible to a very small diameter in order that it may be placed in position within the abdominal or thoracic aorta by a catheter via the lumen of the femoral artery. Such a procedure obviates the need for a major surgical intervention, and reduces the risks associated with such a procedure.

[0008] Other stent/graft composite devices using a textile fabric are shown in U.S. Patent

No. 5,628,788 to Pinchuck.

[0009] As mentioned above, ePTFE may also be used as graft material in stent/graft endoprostheses. One example of an ePTFE stent/graft device is shown in U.S. Patent No. 5,700,285 issued to Myers, et al. Myers discloses a tubular intraluminal graft in the form of a tubular diametrically adjustable stent having an interior and exterior tubular covering of porous expanded polytetrafluoroethylene. The tubular covering surrounds the stent so that the stent is contained during contraction and expansion in the delivery process.

[0010] Stents are effectively used in combination with grafts as the composite endoluminal prosthesis allows blood flow through the vessel created by the graft, while the stent maintains its patency. It has been found however that stent/graft composite devices exhibit reduced flexibility and longitudinal compliance. Longitudinal compliance is of particular importance to such stent/graft endoluminal prosthesis as the device must be intraluminally delivered through tortuous pathways of a blood vessel to the implantation site where the stent is expanded. The increased width creates a profile of increased size of the prosthesis which may present problems in placing and expanding the prosthesis in smaller arteries and veins which demand a smaller, more flexible endoluminal prosthesis. Such reduction of compliance and flexibility is caused by the increased thickness of the composite device and also by the technique used to secure the stent to the graft.

[0011] In order to solve such problems, several stent/graft devices have been developed. International publication number WO 97/21403 to Prograft discloses a stent graft combination comprising a stent member with an inner and outer surface, a tubular graft member, and a ribbon covering only a portion of at least one of the inner and outer surfaces of said stent member for securing the stent member and graft member to one another. This device uses a broad ribbon in order to increase the potential bonding surface area between the coupling member and the graft member to enhance the structural integrity of the stent/graft device while reducing the total thickness of the composite graft. The coupling ribbon used in the Prograft stent/graft device essentially tracks the path of the stent in coupling the stent to the graft, i.e., the coupling ribbon